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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|-------------------------------|----------------------|---------------------|------------------|
| 10/574,479 | 10/05/2006 | Narito Tateishi | Q94241 | 2355 |
| 65565 SUGHRUE-265 | 7590 06/21/201 5550 | 0 | EXAMINER | |
| 2100 PENNSY | LVANIA AVE. NW | | CARTER, KENDRA D | |
| WASHINGTON, DC 20037-3213 | | | ART UNIT | PAPER NUMBER |
| | | | 1627 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 06/21/2010 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | Application No. | Applicant(s) | | | |
|--|---|---|-----------------------|--|--|--|
| Office Action Summary | | 10/574,479 | TATEISHI ET AL. | | | |
| | | Examiner | Art Unit | | | |
| | | KENDRA D. CARTER | 1627 | | | |
| Period fo | The MAILING DATE of this communication app or Reply | ears on the cover sheet with the c | orrespondence address | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)[\] | Responsive to communication(s) filed on 15 Ma | arch 2010 | | | | |
| - | This action is FINAL . 2b) This action is non-final. | | | | | |
| ′= | <i>,</i> — | | | | | |
| 3)[| Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| | closed in accordance with the practice under Ex pane Quayle, 1935 C.D. 11, 455 O.G. 215. | | | | | |
| Dispositi | on of Claims | | | | | |
| 4)🛛 | 4)⊠ Claim(s) <u>21,22,33,36-39 and 43-47</u> is/are pending in the application. | | | | | |
| | 4a) Of the above claim(s) <u>22</u> is/are withdrawn from consideration. | | | | | |
| 5) | 5) Claim(s) is/are allowed. | | | | | |
| 6)🖂 | 6)⊠ Claim(s) <u>21,33,36-39 and 43-47</u> is/are rejected. | | | | | |
| · · · · · · · · · · · · · · · · · · · | Claim(s) is/are objected to. | | | | | |
| - | Claim(s) are subject to restriction and/or | election requirement. | | | | |
| | on Papers | · | | | | |
| | · The specification is objected to by the Examine | • | | | | |
| • | | | Evaminor | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority u | ınder 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 2) Notic 3) Inforr | t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa | te | | | |

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of March 15, 2010 made to the office action filed December 14, 2009. Claims 21, 22, 33, 37-39, and 43-47 are pending. Claims 21, 33, 37, 38, 43 and 45 are amended, and claims 46 and 47 are new. Claims 1-20, 23-32, 34-36 and 40-42 are cancelled. Claim 22 is withdrawn.

In light of the amendments, the 35 U.S.C. 112, first paragraph rejections of claims 21, 26-31 and 40-42 are withdrawn.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 102(b) and 103(a) rejections were found not persuasive, thus the rejections are upheld and modified due to claim amendments.

The Applicant's arguments are addressed below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 33, 37-39, 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohuchida et al. (US 6,201,021 B1).

Ohuchida et al. teach pentanoic acid derivatives such as 2-propylocanoic acid (see claim 9) that treat neurodegenerative diseases and neuronal dysfunction by stroke or traumatic injury (see abstract; addresses claims 21 and 45). Since 2-propylocanoic acid has both the (R) and (S) enantiomer, the Examiner reads that (2R)-2propylocantoic acid is present. Particularly, the pentanoic acid derivatives elicited potent effects in improving astrocyte functions (see column 27, experiment 1, table 1, lines 40-55; addresses claims 21, 33, 44 and 45), elicited marked regeneration effects of GABA receptor responses against reactive astrocytes wherein the compounds are effective in transforming reactive astrocytes to astrocytes (i.e. acceleration differentiating nerve cell; see columns 27 and 28, tables 2 and 3, lines 63-67; addresses claims 21, 44 and 45) and suppressive effects on on-cell death in symbiotic neuronsastrocytes wherein dendrite generation in the neurons were detected (see column 29, lines 1-31; addresses claims 21, 44 and 45). The astrocyte cultures were isolated from cerebrums of neonatal rats (see column 27, lines 13-18; addresses claims 37-39 and 45).

The Examiner would like to note that although stem cells or precursor cells are not taught, the claims are drawn to a method of administering the same compound taught by Ohuchida et al., thus the properties of the compound (i.e. diffentiation and/or proliferation of a cerebral nerve stem cell or cerebral nerve precursor cell) is inherent. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established. Thus, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 43, 46 and 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ohuchida et al. (US 6,201,021 B1) as applied to claims 21, 33, 37-39, 44 and 45 above in view of Mazo (Pittsburgh Post Gazette, April 12, 2000, pages 1-3).

The teaching of Ohuchida et al. are as applied above for claims 21, 33, 37-39, 44 and 45.

Ohuchida et al. does not teach that the cells are for transplant.

Mazo teach that brain cell transplants are known to be successful for the treatment of stroke (see page 1).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the teaching of Ohuchida et al. and to transplant the regenerated nerve cells because it has been successfully used in the treatment of stroke.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. The Applicant's arguments regarding the 35 U.S.C. 112, first paragraph rejections are moot due to the withdrawal of the rejections.

The Applicant's argue that Ohuchida et al. does not teach stem or nerve precursor cells, but astrocytes which are already nerve cells. Mazo does not cure the deficiencies of Ohuchida et al.

The Examiner disagrees because although the Applicant's may have been the first to appreciate the effects of (2R)-2-propyloctanoic acid in cerebral nerve stem cells or cerebral nerve precursor cells, the current claims are not directed to any particular patient population. The current method claims are only drawn to the method steps of administering (2R)-2-propyloctanoic acid to a mammal, which is taught in the art. The properties of what (2R)-2-propyloctanoic acid does upon administration to a mammal is thus inherent.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kendra D Carter/

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Examiner, Art Unit 1627

/SREENI PADMANABHAN/ Supervisory Patent Examiner, Art Unit 1627